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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,603	07/01/2003	Colombe Chappey	11068-065-999	4793
20583	7590	02/04/2010		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER HUMPHREY, LOUISE WANG ZHIYING	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 02/04/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/612,603	<b>Applicant(s)</b> CHAPPEY ET AL.	
	<b>Examiner</b> LOUISE HUMPHREY	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,12,13,21,24,25,29,31 and 39-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,12,13,21,24,25,29,31 and 39-60 is/are rejected.
- 7) ☒ Claim(s) 1,42 and 60 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 January 2010 has been entered.

**DETAILED ACTION**

This Office Action is in response to the amendment filed on 15 January 2010.

Claims 2-11, 14-20, 22, 23, 26-28, 30, and 32-38 have been cancelled.

Claims 43-60 have been added.

Claims 1, 12, and 42 have been amended.

Claims 1, 12, 13, 21, 24, 25, 29, 31 and 39-60 are pending and currently examined.

***Claim Objections***

Claims 1, 42 and 60 are objected to because of the following informalities:

Claim 1 contains an extra comma after the phrase "I47V" in line 10; and the phrase "whether the protease encoded by said HIV-1 exhibits" seems extraneous in the context of method step "detecting... the presence of a mutation associated with reduced susceptibility to treatment with said protease inhibitor..." in lines 3-4. Applicants may consider deleting the phrase "whether the protease encoded by said HIV-1 exhibits" in order to clarify the claim limitation as a positive method step.

Claim 42 is objected to because of grammatical errors: *i.e.* the word “mutation” in singular form does not agree with the multiple amino acid positions; and the extra commas after the numbers “7” and “8.” Applicants may consider amending the claim to recite: "wherein the method comprises detecting mutations associated with reduced susceptibility to treatment with said protease inhibitor in at least 2, 3, 4, 5, 6, 7 or 8 of the amino acid positions."

Likewise, claim 60 is objected to because of the same grammatical errors.

Appropriate correction is required.

### **WITHDRAWN REJECTION**

The rejection of claims 1, 12, 13, 18, 21, 24, 25, 29, 31 and 39-42 under 35 U.S.C. §102(b) as being anticipated by Palmer *et al.* (1999) is withdrawn in response to Applicant's amendment.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 12, 13, 21, 24, 25, 29, 31 and 39-42 have been considered but are moot in view of the new ground of rejection.

### **NEW REJECTION**

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 12, 13, 21, 24, 25, 29, 31, and 39-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Carrillo *et al.* (1998, No. B17 in IDS filed on 17 February 2006, hereinafter "Carrillo").

Claim 1 is directed to a method for determining whether a human immunodeficiency virus type 1 (HIV-1) has an increased likelihood of having a reduced susceptibility to treatment with amprenavir, comprising: detecting the presence of one mutation at amino acid position 11, 34, 47, 50, 76, 83, 91 or 95 of an amino acid sequence of said protease, with the proviso that said mutation is not I47V or 150V, and wherein the level of susceptibility, mutations, and position number are compared to the protease sequence of the NL4-3 reference strain.

Claim 42 further limits claim 1 to detect multiple mutations in at least 2, 3, 4, 5, 6, 7, or 8 of the positions. Claim 43 further limits claim 1 to additionally detecting at least one mutation at amino acid 32, 33, 43, 46, 48, 54, 58, 71, 79, 82 or 84, with the proviso that the mutation is not V32I, M46I, M46L, I54L, I54M, or I84V. Claim 60 further limits claim 43 to detect multiple mutations in at least from 2 to 19 of the positions.

Carrillo teaches detection of mutations in the protease gene of HIV-1 strain NL4-3 after treatment with a protease inhibitor (page 7532, right column, lines 12-16 of the full paragraph). By sequence analysis of the protease coding region from HIV-1 passaged with a protease inhibitor, the following claimed mutations are identified: L33I,

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E34A, E34K, A71V, L76V, V82A and T91S (see page 7534, Figure 2) when compared with the protease sequence of wild-type NL4-3 strain.

The phrase “for determining whether a HIV-1 has an increased likelihood of having a reduced susceptibility to treatment with amprenavir”, “associated with reduced susceptibility to treatment with said protease inhibitor” and “wherein the presence of said mutation indicates that the HIV-1 has an increase likelihood of having reduced susceptibility to treatment with amprenavir” are the intended use and newly discovered properties of the prior art method step and thus are inherently anticipated by Carrillo.

A rejection under 35 U.S.C. §102 or §103 can be made when the prior art product seems to be identical except that the prior art is silent as to an inherent characteristic (MPEP §2112). According to M.P.E.P. § 2112 [R-3], “[t]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentable.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Newly discovered property of prior art cannot support patent on that same art. See MPEP §2112 [R-3]. *Abbott Laboratories v. Baxter Pharmaceutical Products Inc.* 80 USPQ2d 1860, U.S. Court of Appeals Federal Circuit Nos. 06-1021, -1022, -1034. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1251, 1254, 195 USPQ 430, 433 (CCPA 1977). See MPEP §2112.02 for guidelines on inherency for process claims.

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The wherein clauses in claims 12, 13, 21, 24, 25, 29, 31, 39-41 and 44-59 are not given patentable weight because they do not materially add limitations to the physical method step of detecting amino acid mutation(s) at the recited position(s) in the claimed invention. Therefore, the wherein clauses are anticipated since Carrillo teaches the method of detecting mutations at the claimed amino acid positions.

Where, as here, the Patent Office lacks the facilities to perform comparisons between the claimed material and prior art materials that reasonably appear to meet the claim limitations, the burden is properly shifted to applicant to distinguish the claimed product from the prior art product. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977); *Ex Parte Gray*, 10 USPQ2nd 1922 (BPAI 1989). Patent owner's burden under the circumstances presented herein was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. §102, on 'prima facie obviousness' under 35 U.S.C. §103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

Absent evidence to the contrary, it appears that the mutations in the method taught by Carrillo anticipate the instantly claimed invention. Applicants need to provide some showing to distinguish the claimed invention from the cited prior art.

### ***Conclusion***

No claim is allowable.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louise Humphrey/  
Examiner, Art Unit 1648